

<b>Document filename:</b> HPV-PS User guide			
<b>Directorate / Programme</b>		<b>Project</b>	Cytology
<b>Document Reference</b>			
<b>Project Manager</b>		<b>Status</b>	Approved
<b>Owner</b>		<b>Version</b>	V 1.0
<b>Author</b>		<b>Version issue date</b>	18/04/2013

# HPV Primary Screening User Guide

**April 2013**

**Amendment History:**

Version	Date	Amendment History
Draft	29/11/2012	1 <sup>st</sup> draft copy of user guide
1.0	18/04/2013	Pilot review

**Forecast Changes:**

Anticipated Change	When

**Reviewers:**

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**Glossary of Terms:**

List any new terms created in this document. Mail the NPO Quality Manager to have these included in the master glossary above [1].

Term	Acronym	Definition

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## 1 Introduction

In the next few years the NHS Cervical Screening Programme is expected to move entirely from primary screening by cytology, with or without HPV triage, to primary screening by HPV testing. Cytology testing will be undertaken only for those women who were positive for high-risk HPV infection.

This screening method is radically different in as much as an HPV test is performed initially & only if the HPV Result is positive (infection code 9) is a cytology test undertaken. A new result code of X (dummy code) is to be introduced to record tests where the HPV test was negative therefore a cytology test was not required. Codes are as follows:

Result Code	Description
0	"?Glandular neoplasia (non cervical)"
1	"Inadequate"
2	"Negative"
3	"Low grade dyskaryosis" (CIN1)
4	"High grade dyskaryosis (severe)" (CIN3)
5	"High grade dyskaryosis ?invasive squamous carcinoma"
6	"?Glandular neoplasia of endocervical type"
7	"High grade dyskaryosis (moderate)" (CIN2)
8	"Borderline change in squamous cells"
9	"Borderline change in endocervical cells"
B	"Borderline change in squamous cells (HPV tested)"
E	"Borderline change in endocervical cells (HPV tested)"
G	"?Glandular neoplasia (non cervical)(HPV tested)"
M	"Low grade dyskaryosis (HPV tested)"
N	"Negative (HPV tested)"
X	"No Cytology result (HPV Primary)" – may only be used if HPV primary screening test

### Infection codes

- 0 HPV Negative
- 9 HPV Positive
- U HPV Unreliable/inadequate
- Q No HPV undertaken**

## 2 Result/Infection/Action Code Combinations

The new valid Result/Infection/Action code combinations are as follows:

Result Code	Infection Code(s)	Action Code(s)
X	0 or U	R
X	0	A
X	0, 9 or U	S
1	9 or Q	R or S
0	9 or Q	R or S
2	9 or Q	R or S
3	9 or Q	S
4	9 or Q	S
5	9 or Q	S
6	9 or Q	S
7	9 or Q	S
8	9 or Q	S
9	9 or Q	S

### 3 System Changes

The introduction of these result codes has impacted on several core areas of the current system. These areas are as follows:

- FD Screen – HA Details
- DD Screen – Pages 3, 6 & 7
- Introduce new screen (HP) for setting up letter Id's etc for HPV Primary screening
- Laboratory Links
- Manual Matching Screen (MM)
- CY Screen – Cytology Tests
- AJ-CD – Deducted tests print/ HA-HA transfer of deducted tests/redirected tests
- AJ-CIN – HA-HA transfer of deducted tests/redirected tests
- AJ-CP – Result Letter Print
- AJ-RP – Invitations, Reminders, First/Final Non-responders etc.
- CSSE – Enquiry Package (To be amended & released separately)
- KC53 – Statistics (To be amended & released separately)

### 4 FD Screen Changes

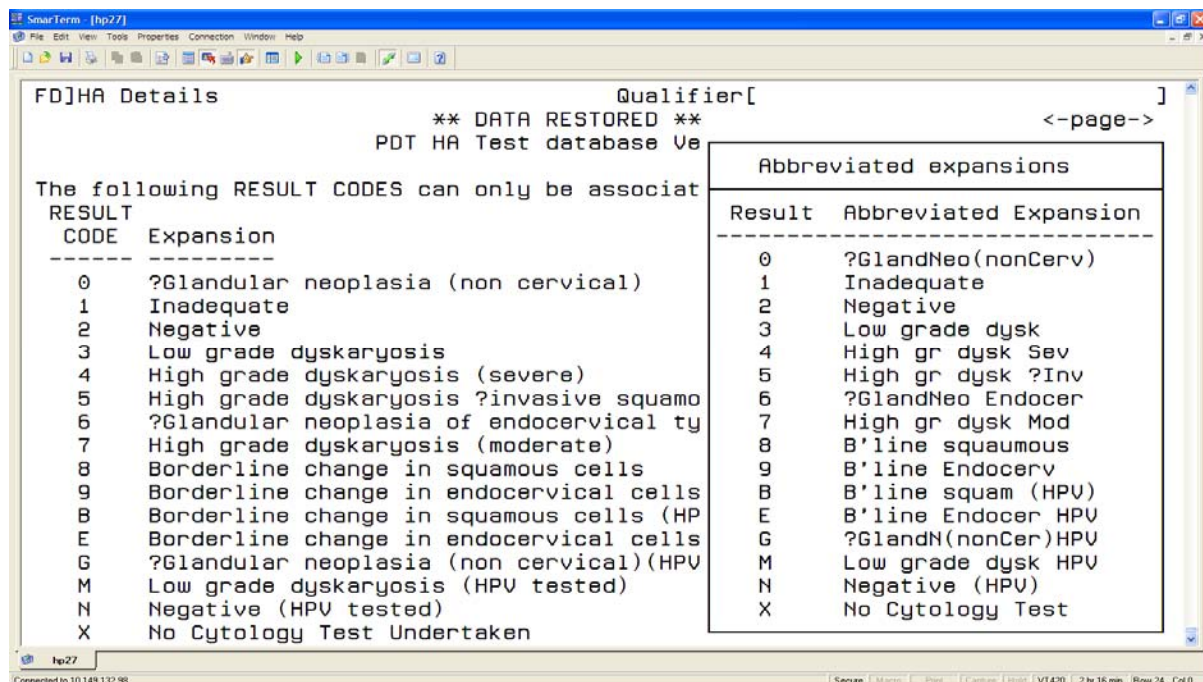
#### 4.1 Page 5 Changes

Changes have been made to page 5 of the FD screen to include new result code X and HPV Primary Screening Result/Action combinations.

RESULT CODE	Expansion	Action Codes
0	?Glandular neoplasia (non cervical)	A, H, R, S
1	Inadequate	H, R, S
2	Negative	A, H, R, S
3	Low grade dyskaryosis	R, S
4	High grade dyskaryosis (severe)	S
5	High grade dyskaryosis ?invasive squamous carcinoma	S
6	?Glandular neoplasia of endocervical type	S
7	High grade dyskaryosis (moderate)	S
8	Borderline change in squamous cells	R, S
9	Borderline change in endocervical cells	R, S
B	Borderline change in squamous cells (HPV tested)	A, R, S
E	Borderline change in endocervical cells (HPV tested)	A, R, S
G	?Glandular neoplasia (non cervical)(HPV tested)	A, R, S
M	Low grade dyskaryosis (HPV tested)	A, R, S
N	Negative (HPV tested)	A, R, S
X	No Cytology Test Undertaken	A, R, S

The pop-up window to display the abbreviated expansion for each result code has been amended to include the new 'X' result code. These abbreviations are used throughout the system for reports and are limited to 18 characters.

This pop-up window can be accessed from the KEY field in the normal way.



## 4.2 Page 9 Changes

New result/action codes have been added to allow anticipated (estimated) delivery days to be set. A PSAU will be issued to set up new 'Estimated days to delivery' for the new 'X' result code.

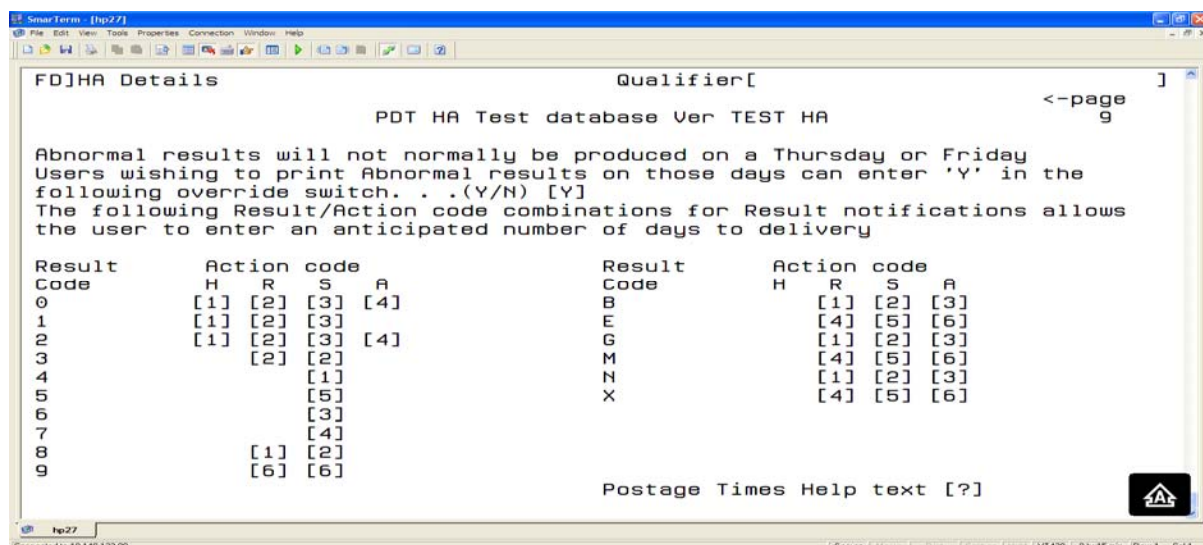
**Action:** Please note that the number of days will be set initially to 1. This is the minimum allowed so you may wish to alter the number of days.

### 4.2.1 Display Screen

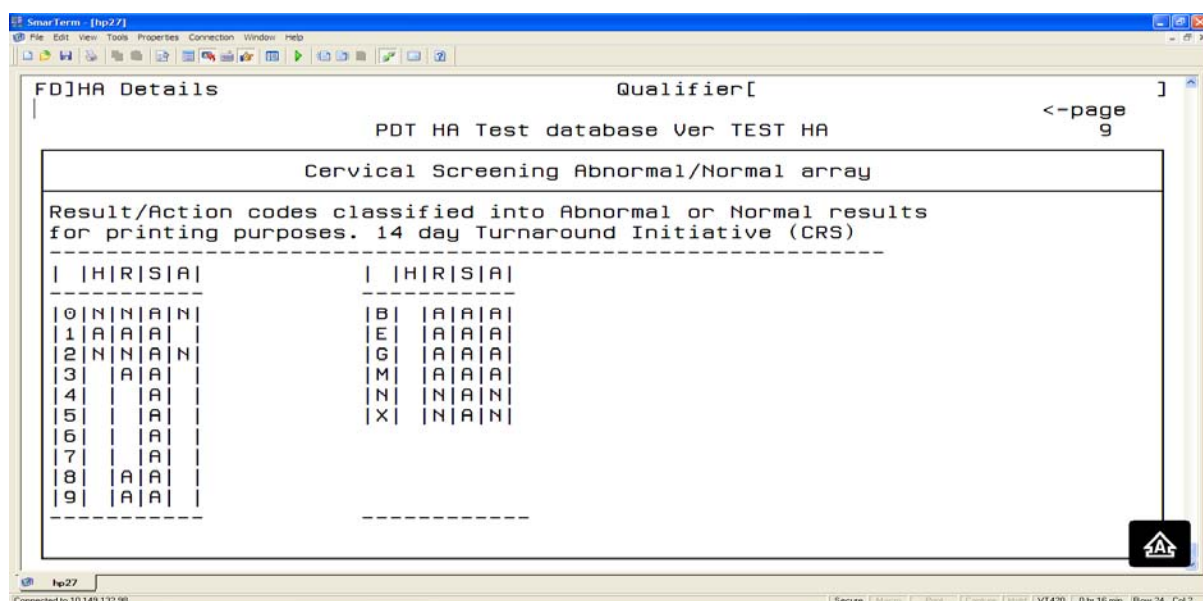
The PSAU will install the new result /action codes, pre-set to 1 day for the anticipated number of days to delivery.

**Action:** It is up to each PCO to reset the number of days in line with policy.

This number of days setting is required for the calculation and setting of the anticipated date of delivery of a cytology result letter. This date is used to calculate the 14 day turnaround figures (CSSVSA – vital signs monitoring).



The pop-up window that is accessed via the KEY field on page 9 to display abnormal results for CP printing has also been amended to include the new result codes.



#### 4.2.2 Page 9 Validation

Amend validation to check a numeric value in the range 1-6 is correctly entered against each new result/action code.

If a value other than 1, 2, 3, 4, 5 or 6 is entered the appropriate REJECT error message is displayed. Available error messages are:

1. Value is greater than 6
2. Value not > '0'
3. Value not numeric

Example:



SmartTerm - [hp27]

FD]HA Details REJECT Qualifier[ ]

1. Value is greater than 6 <-page 9

PDT HA Test database Ver TEST HA

Abnormal results will not normally be produced on a Thursday or Friday  
 Users wishing to print Abnormal results on those days can enter 'Y' in the  
 following override switch. . .(Y/N) [Y]  
 The following Result/Action code combinations for Result notifications allows  
 the user to enter an anticipated number of days to delivery

Result Code	Action code				Result Code	Action code			
	H	R	S	A		H	R	S	A
0	[1]	[2]	[3]	[4]	B		[1]	[2]	[3]
1	[1]	[2]	[3]		E		[4]	[5]	[6]
2	[1]	[2]	[3]	[4]	G		[1]	[2]	[3]
3		[2]	[2]		M		[4]	[5]	[6]
4			[1]		N		[1]	[2]	[3]
5			[5]		X		[7]	[5]	[6]
6			[3]						
7			[4]						
8		[1]	[2]						
9		[6]	[6]						

Postage Times Help text [?]

hp27

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#### 4.2.3 Update

New values will be updated onto the 'Anticipated no of days file. The change is captured on the FD screen audit file and may be viewed via the pop-up window. The pop-up window is accessed from the Qualifier field in the normal way.

SmartTerm - [hp27]

FD]HA Details Qualifier[ ]

PDT HA Test database Ver TEST HA <-page 9

Abnormal results will not normally be produced on a Thursday or Friday  
 Users wishing to print Abnormal results on those days can enter 'Y' in the  
 following override switch. . .(Y/N) [Y]  
 The following Result/Action code combinations for Result notifications allows  
 the user to enter an anticipated number of days to delivery

Cervical Screening Audit of Changes Screen 9 of FD Application				
Date of Change	Field Identifier	Previous Value	Category Initials	
15.01.2013	CP XA Post	1	FULS	FS
15.01.2013	CP XS Post	6	FULS	FS
05.12.2012	CP XA Post	5	IAXX	IA
05.12.2012	CP XS Post	1	IAXX	IA
05.12.2012	CP 5S Post	2	IAXX	IA
05.12.2012	CP NA Post	1	IAXX	IA
05.12.2012	CP NS Post	1	IAXX	IA
05.12.2012	CP NR Post	1	IAXX	IA

>>

hp27

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Secure Macro Print Capture Hold VT420 2 hr 25 min Row 24 Col 2

## 5 DD Screen

### 5.1 Page 3

A small change to add Result code 'X' to 'Suspended' defaults.

DD]District Data Qualifier[EX] <-page->

EXETER MAXIMUM LENGTH DISTRICT District

ACTION CODE MONTHS (District Policy - Standard age range)

A 60

ACTION CODE MONTHS

R U

ACTION CODE MONTHS

S [13] Default for '0S, 2S, GS, NS & XS' Tests (Max 15 Months)

[11] Default for other 'S' Tests (Max 12 Months)

An ACTION CODE of 'H', irrespective of the RESULT CODE, will leave the patient's Status UNALTERED.

### 5.2 Page 6

New result 'X' has been added to the 'Suppress' printing of the next test due date screen.

DD]District Data Qualifier[EX] <-page->

EXETER MAXIMUM LENGTH DISTRICT District

Suppress the printing of Next Test Due Date on the following:

All RP Letters: [ ] All CP Letters: [ ]

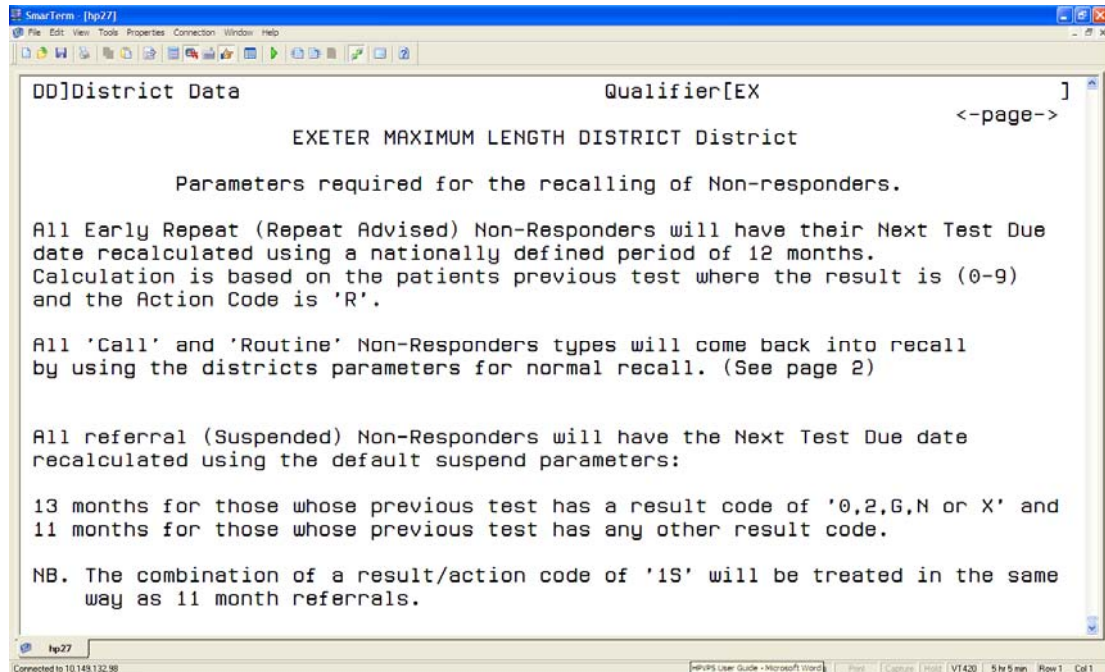
RP Letters						CP Letters							
Res	H	R	S	A		Res	H	R	S	A			
0	[ ]	[Y]	[Y]	[Y]	B	[Y]	[Y]	[Y]	[Y]	B	[Y]	[Y]	[Y]
1	[Y]	[Y]	[Y]		E	[Y]	[Y]	[Y]		E	[Y]	[Y]	[Y]
2	[Y]	[Y]	[Y]	[Y]	G	[Y]	[Y]	[Y]	[Y]	G	[Y]	[Y]	[Y]
3		[Y]	[Y]		M	[Y]	[Y]	[Y]		M	[Y]	[Y]	[Y]
4			[Y]		N	[Y]	[Y]	[Y]		N	[Y]	[Y]	[Y]
5			[Y]		X	[ ]	[ ]	[Y]		X	[ ]	[Y]	[ ]
6			[Y]					[Y]					
7			[Y]					[Y]					
8		[Y]	[Y]					[Y]	[Y]				
9	[ ]	[ ]	[ ]					[Y]	[Y]				

Enter a 'Y' in the 'All Letters' fields only if postponement of Call/Recall is required. Otherwise enter 'Y' selectively for each Result/Action Code.

**ACTION:** Please note new fields for Result code 'X' will initially be blank, and will require setting up if your organisation uses NHAIS letters and wishes to suppress the printing of the next test due date.

### 5.3 Page 7

Result code 'X' added to the parameter information screen for the recalling of Non-responders.



## 6 HP screen (HPV Primary Letters)

In order to avoid numerous result combinations from being added to the already weighty DD screen, a new screen (HP) has been developed to handle the letter requirement parameters for HPV primary screening invitations, reminders and results.

It is worthwhile thinking of the HP screen as an extension to the DD screen.

The screen is accessed by entering a key of **HP** and a qualifier of the required existing DHA code. The HP screen will be pre-populated for each of your existing districts as shown below.

HP]HPV Primary Letters Qualifier[HP

HPV PS DISTRICT District

Produce HPV Primary Invites/Reminders for this District? (incl Call)...[N]

Invitation Letter XA-1 [ ] Standard Alternative Orig Dest  
Reminder Letter XA-2 [ ] [D] [P] - Applied to ALL Inv/Rem

Auto-Cease (following X0A) PX0C [ ] [D] [P]

Res	REPEAT MONTHS		STANDARD LETTERS			ALTERNATIVE LETTERS			RESULT	
	Lower	Upper	Inv	Rem	Res	Inv	Rem	Res	Orig	Dest
X0A	36	60	XA-1	XA-2	PX0A	[ ]	[ ]	[ ]	[D]	[P]
X0R	36	36	XA-1	XA-2	PX0R	[ ]	[ ]	[ ]	[D]	[P]
X0S	15	15	XA-1	XA-2	PX0S	[ ]	[ ]	[ ]	[D]	[P]
X9S	15	15	XA-1	XA-2	PX9S	[ ]	[ ]	[ ]	[D]	[P]
XUR	3	3	XA-1	XA-2	PXUR	[ ]	[ ]	[ ]	[D]	[P]
XUS	15	15	XA-1	XA-2	PXUS	[ ]	[ ]	[ ]	[D]	[P]
09R	12	12	XA-1	XA-2	P09R	[ ]	[ ]	[ ]	[D]	[P]
09S	15	15	XA-1	XA-2	P09S	[ ]	[ ]	[ ]	[D]	[P]

hp27.stw

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Line 3 displays the name of the district, followed by a (Y/N) flag indicating whether the district is designated as producing HPV Primary Screening Invitations or not.

Essentially, this flag controls whether AJ-RP will use the HP or the traditional DD screen parameters when producing Invitations and Reminders for this District. This is explained in more detail below.

This field will be pre-populated with a value of N for each of your districts.

*Note that the HP screen settings will ALWAYS be used to produce Invitations and Reminders for women following an HPV Primary result, since these result combinations are not defined on the DD screen.*

The following table indicates which screen AJ-RP will pick up its letter parameters from:

Latest Test Result Type	District Inv/Rem setting (line 3 of HP screen)	Screen used for Letters
HPV Primary	Y	HP
HPV Primary	N	HP
Non Primary	Y	HP
Non Primary	N	DD

Below this flag is a small table which controls the general letter settings for Invitations and Reminders, as well as those for the Auto-Cease (due to age) letter.

In this table, each letter type has up to four column entries:

Standard	-	The Standard letter code in use* (READ-ONLY.)
Alternative	-	Alternative Letter Code to use. (must be defined in LL)
Orig	-	Letter Originator - only F, D or G permitted.
Dest	-	Letter Destination – must be P.

*\*Dummy LL entries have been automatically generated for all standard codes*

Invitation and Reminders always share the same Originator and Destination values and these apply to ALL HPV Primary invites/reminders, regardless of latest result.

*The letter codes for Invites and Reminders defined here may be further overridden for individual result codes by filling in the appropriate column in the results table. (see below)*

Auto-Cease (following X0A) -

Should a woman receive an X0A result and the calculated NTD date take her beyond the upper age limit for screening, the system will cease her due to age subject to auto-ceasing rules.

The standard letter produced will be the PXOC result letter (with Originator and Destination as defined on this row.)

The Alternative result field can be used if a code other than PX0C is required for a particular district

## General results table

A single row will be displayed for each valid HPV primary screening Result/Infection/Action result combination

Each row is divided into columns which display the parameters used by this district. The left hand side of the screen is for information only, with the right hand side displaying configurable parameters.

## READ-ONLY FIELDS

### Res

This column indicates the result combination for which this row's parameters apply.

### REPEAT MONTHS

Divided into *Lower* and *Upper* (age ranges,) these two columns indicate the number of months automatically added to the Next Test Due (NTD) date upon adding an HPV Primary test with this result depending on which age category the woman was in *on the date the sample was taken*.

Results with an action of S will utilise the standard recall interval for suspended tests as defined on the DD screen.

### STANDARD LETTERS

Divided into three columns for **Invitation**, **Reminder** and **Result**, these values show the default letter code which the system will attempt to produce for that scenario.

The standard INV and REM codes displayed on each line may change depending on whether this is an HPV primary district or not and also whether alternative default *Call / Inv / Rem* fields above have been defined.

## **EDITABLE FIELDS**

### **HPV Primary Screening flag**

The HPV primary screening flag governs the type of Invites/Reminders produced for a given District and must be set to N or Y. It must be set to Y if the District receives and handles HPV Primary Screening results.

**Error Message:** - 'Must be Y or N'

**Query Message:**

"District now/no longer HPV PRIMARY?" - Confirm if you wish to change the HPV Primary status of this district

### **ALTERNATIVE LETTERS**

Likewise, divided into three columns, these fields store the letter codes which this district should use instead of the standard equivalent letter code.

These fields should be left blank unless you have a specific business requirement to produce an alternative letter for a particular result combination or district (*e.g. removing references to a woman's GP for the ZZ district.*)

Permitted Values:	<b>AS</b>	-	<b>Address Slips</b>
	<b>AL</b>	-	<b>Address Labels</b>
	<b>XXXX</b>	-	<b>Valid Letter Code</b>
			<b>(Up to 4 characters, as defined on the LL screen)</b>

**Error Messages:**

"LETTER undefined"	-	Letter code must be defined on LL screen unless using AS or AL for slips and labels.
--------------------	---	--

**Query Messages:**

amend Std INV lett?	-	Confirm if you wish to override the standard Invitation letter code for this district.
amend Std REM lett?	-	Confirm if you wish to override the standard Reminder letter code for this district.

### **Orig**

The letter originator used for this combination. This is a mandatory field.

Permitted Values:	<b>D</b>	-	<b>District</b>
	<b>F</b>	-	<b>FHSA</b>
	<b>G</b>	-	<b>GP</b>

<b>Error Messages:</b>	"ORIG missing"	- Must contain a value.
	"ORIG must be D, F or G"	- Only permitted values.



**Query Message:**

amend ORIG for ALL Inv/Rem? - A reminder that this field applies to ALL Invitations and Reminders for this district.

**Dest**

The letter destination used for this combination. This is a mandatory field.

Permitted Values: **P** - **Patient** (This is the only allowed value)

**Error Messages:** "DEST missing" - Must contain a value.  
 "DEST must be P" - Only permitted value.

**7 Laboratory Links Changes****7.1 AJ-CLLM Validation**

The laboratory links application has been changed to receive and validate the new HPV Primary Screening test results and the new HPV Primary screening marker.

The HPV Primary Screening marker will be set to 'Y' (HPV Primary screening test), 'S' (HPV Primary Screening test Self Sample) or 'N' (Not an HPV Primary Screening test). Initially the marker will only be set at HPV-PS pilot laboratories, at all other laboratories the HPV Primary Screening Marker will be set to null. Any markers set to null will be set to 'N' by the Lab Links application.

For new valid Result/Infection/Action code combinations are as follows:

Result Code	Infection Code(s)	Action Code(s)
X	0 or U	R
X	0	A
X	0, 9 or U	S
1	9 or Q	R or S
0	9 or Q	R or S
2	9 or Q	R or S
3	9 or Q	S
4	9 or Q	S
5	9 or Q	S
6	9 or Q	S
7	9 or Q	S
8	9 or Q	S
9	9 or Q	S

Table 1

Only result codes 0-9 and "X" are valid if the HPV Primary flag is set. All other result codes (such as B, E, G, M or N) will be rejected. Only the combination of result/infection/action as outlined above will be accepted as valid. Any other combination will be rejected as invalid.

Repeat months will be calculated by the Lab Links software based on the result/infection/action combination, age of patient and District settings. Result/infection/action combination "X0R", repeat months of 36 can be overridden by an alternative value sent from the Laboratory (currently 12 months).

Validation messages will be added to Insufficient Information on the AJ-CLLM report.

## 7.2 Manual Matching Screen

### 7.2.1 MM Display

The MM screen displays test results that were found to be:

- Partially Matched i.e. Possible/Fuzzy matches
- NON Hits (no match found on either Live or Deducted database)
- Non Redirected Test results (Test date dated after date of deduction)

The 3 screen displays have been amended to add the infection code to the test data details and to highlight a test result where the HPV Primary screening marker is set. If the HPV Primary screening marker is set, 'HPV-PS' will be hi-lighted next to 'Lab Details'.

See example below of MM-F screen for HPV Primary screening below:

```

SmarTerm - [hp27.stw]
File Edit View Tools Properties Connection Window Help

MM]Lab Links Manual Matching      Qualifier[1928877/1,1,12007659      ]
                                     page->

-----
Lab No: 60020   File Ref: 928877/1   Code F   05.11.11 - 07.11.11   Balance = 2
-----

                        ** FUZZY MATCH **
Lab Details HPV-PS      HA Details(1 of 2)
                        LIVE Database
Matching Code      :      A3 NHS NUMBER match
NHS Number        : 650 014 2225
Surname           : JOUSAR
Forenames         : JAUSAR
Date of Birth     : 25.12.1976
Prev. Surname     : LORINA M
Alt. Surname      : 25.12.1976
                  : JENKINS

Address at Lab    : 11 Cedar Drive,
Address at HA     : 100 Newtown Street %Abbar,
Test Data         : Slide No : 12007659   Result Code : 2   Rpt in :
                  : Test Date : 24.11.2012   Action Code : R   Infection : Q

Action [ ]

-----
Action Codes: (X)Non-Hit, 'H'it, 'N'ext Lab Rec, 'P'rev Lab Rec, 'Q'uit
-----
hp1.stw hp27.stw
Connected to 10.149.132.98
Secure Mouse Print Capture Mail VT420 3 hr 48 min Row 1 Col 1

```

### 7.2.2 MM Screen Validation

When a woman is matched on the MM screen (MM-F or MM-N) the test will be validated the same as in AJ-CLLM.

Validation messages will be added to Insufficient Information on the AJ-CLLP report.

## 7.3 CLLM/CLLP Reports and Residual Cards

### 7.3.1 Residual Cards

The HPV Primary screening marker will be displayed on the residual card. This is necessary because the Card can be sent to another PCO area and used to manually update the test result via the CY screen.



Residual Cards are produced for:

- N Non-Hit
- I Insufficient Information
- D Invalid for DHA/Slide
- R Rejections

```
12004433 Bishop Auckland, Co. Durham
File REF: 91020/2                      National Lab Code : 60020

CERVICAL CYTOLOGY LABORATORY LINK
Smear test details unmatchable at PDT HA Test database Ver TEST HA
REJECTED TESTS      (SECTION R) Printed: 22-NOV-2012 at 12:35 PM
Reason for rejection - NO CYP

Wool Wendy

NHS Number: 999 788 7745              Date of Birth: 7.7.1951

Address: 79 East Make Believe Hill Exeter
Slide No.: 12004433   Test Date: 16.11.2012
Standard Result: 3 Low grade dysk      Action: R   Repeat in 06 months
TES Sender Code: TORHOS      Infection Code: 3   HPV-PS: N
TES Sender Details: The Big Hospital, 267 The Road XXXXXXXXXXXXXXXX, Lawes Bridg
```

### 7.3.2 Reports

Laboratory Links and the MM screen both produce a matching report. This report is split into many sections. These sections are as follows:

- HITS (Live)
- HITS (Deducted)
- ADDRESS HITS
- POSSIBLE HITS (LIVE & DEDUCTED)
- MANUAL HITS (LIVE)
- MANUAL HITS (DEDUCTED)
- No of Tests Redirected
- No of Tests NOT REDIRECTED
- NON-HITS
- INVALID INPUT
- INVALID FOR HA/SLIDE
- REJECTED TESTS

The HPV Primary screening marker flag will be displayed on all these reports.

### 7.3.3 Error messages

Five new error messages have been introduced and will appear on the Laboratory Links Matching/Error reports and the Residual Cards. They are:

1. HPV Primary screening flag invalid - must be 'Y', 'S' or 'N'. Contact the Laboratory.  
Residual Cards message: HPV PRIMARY FLAG INVALID

(This message will apply to any test where the HPV Primary screening flag is not set to 'Y', 'S', 'N' or null. Null will be allowed and set to 'N' to allow for Labs that have not amended their system to allow for HPV Primary screening.)

2. HPV Primary test result is invalid. Contact the Laboratory.

Residual Cards message: HPV-PS INVALID RESULT/INFECT/ACTION

(This message will apply to any test where the HPV Primary screening flag is set to 'Y' or 'S' and the result, infection, action code is missing, invalid or an invalid combination. The relevant message will be added to the report but not the residual cards:-

- Result missing
- Infection missing
- Action missing
- Result invalid
- Infection invalid
- Action invalid
- Invalid combination)

3. Third consecutive HPV positive, Cytology negative result - action should be 'S'. Colposcopy required. Contact the Laboratory.

Residual Cards message: 3RD HPV POS - COLP REQ

(This message will apply to any test where the HPV Primary screening flag is set to 'Y' or 'S' and the previous 2 negative tests (result codes 0 or 2) had an action code of 'R' and the new test has an action code of 'R'.

The new test must have an action code of 'S'.)

4. Third consecutive Inadequate/Unreliable result - action should be 'S'.

Colposcopy required. Contact the Laboratory.

Residual Cards message: 3RD INAD RES - COLP REQ

(This message will apply to any test where the HPV Primary screening flag is set to 'Y' or 'S' and the previous 2 tests were combinations of '19R' or 'XUR' and the new test is a combination of '19R' or 'XUR'. The new test should have an action code of 'S'.)

5. HPV Primary test result is invalid for test that is not HPV-PS. Contact the Laboratory.

Residual Cards message: HPV-PS INVALID TEST RESULT NON HPV-PS

(This message will apply to any test where the HPV Primary screening flag is set to 'N' or null and the result or infection code is set to a code that applies to a HPV-PS test only. The relevant message will be added to the report but not the residual cards:-

- Infection 'Q' invalid
- Result 'X' invalid)

## 8 CY Screen Changes

### 8.1 Display

A new data field HPV Primary has been added to the CY screen. This data field is the HPV Primary screening flag and is a mandatory data field.

#### Sample Input Screen

CY]Cytology Test		Qualifier[977 752 1324		] page->	
HPV Patient		DoB: 09.06.1962		Age: 50	
Extra Name:		Q Code:QT1	Dr. V Ermillion		Code: 000030
10 Any Old Road, EXE		Nat/Local District Code: E10/EX			
EX1 9CC					
Amend/Delete previous tests [N] Delete ALL Tests [NO ]					
		PNL Date:		Invited :UNAVAIL	
Next Test due [28.04.2013]		Recall Type [I] Early Repeat (Inadequate)			
Notif Date [22.01.2013]		Recall Status [1] Patient Informed			
-----					
National Code [ ]		Slide No. [ ]			
Test Date [ ]		Sender National Code [ ]			
Result Notif [ ]		Source [ ] Sender [ ]			
Result Code [ ]		Inf [ ] Action Code [ ]		Rpt in [ ] Months HPV Primary? [ ]	
Correspondence? Y		Age at test date		Input date Screening HA [TES]	
Comment[				]Complete?[ ]	
[				]Susp List[Y]	
[				]Susp List[Y]	
Test 0 of 3 -----T--Flags-----					
Test Date	Result	Infection	Action Code	Rpt Mths	HPV Primary NB:
28.12.2012	1	9	R	04	Y FP69: FNR:
14.01.2012	1	9	R	02	Y POS/DOUBT :N
12.12.2011	2		A	36	Y AGE at NTD:

#### Sample Test Result Display Screen

The HPV Primary Flag will be displayed in reverse video & blink.

CY]Cytology Test		Qualifier[977 752 1324		] <-page->	
HPV Patient		DoB: 09.06.1962		Age: 50	
Extra Name:		Q Code:QT1	Dr. V Ermillion		Code: 000030
10 Any Old Road, EXE		Nat/Local District Code: E10/EX			
EX1 9CC					
		PNL Date:		Invited :UNAVAIL	
Next Test due 28.04.2013		Recall Type I		Early Repeat (Inadequate)	
Notif Date 22.01.2013		Recall Status 1 Patient Informed			
-----					
National Code 60020		BISHOP AUCKLAND, CO. DURHAM		Slide No. 12090897	
Test Date 28.12.2012		Sender National Code 880030			
Result Notif		Source G Sender 000030		Dr. V ERMILLION	
Result Code 1		Inf 9 Action Code R		Rpt in 04 Months HPV Primary? Y	
Correspondence? Y		Age at test date 50		Input date 22.01.2013 Screening HA TES	
Comment					
				Susp List Y	
Test 1 of 3 ----- Previous Recall Type: R Status: - -----T--Flags-----					
Test Date	Result	Infection	Action Code	Rpt Mths	HPV Primary NB:
14.01.2012	1	9	R	02	Y FP69: FNR:
12.12.2011	2		A	36	Y POS/DOUBT :N
					AGE at NTD:

## 8.2 Validation

Changes have been made to the validation routine to accommodate the HPV screening flag and the new result and infection codes and to ensure the correct combinations of result/action/infection and repeat month's values are entered.

The HPV Primary screening flag will identify a test result being entered as a HPV Primary screening result. It must be completed by entering either "N", "S" or "Y".

N = Not HPV Primary Screening

S = Self sampling/tested

(There may be none of these initially – S is to allow for possible future development of self testing)

Y = HPV Primary screening test

If the HPV Primary flag is left blank the following REJECT message will be displayed:

**"HPV PS flag missing"**

If a character other than N, S or Y is entered the following REJECT message will be displayed:

**"HPV PS flag invalid"**

If 'N' is entered in the HPV primary field the test result will be validated as per the 'ABC3' validation rules.

If 'S' or 'Y' is entered the test result will be validated as a HPV Primary screening test result. The following rules apply:

Valid Result/Infection/Action code/repeat months are as follows:

### 0 = "?Glandular Neoplasia (non cervical)"

Result Code	Infection Code	Action Code	Repeat Months	
0	9	R	12 months	Must not be the 3 <sup>rd</sup> consecutive test (excluding inadequate tests) otherwise should be suspended
0	Q	R	12months	Must not be the 3 <sup>rd</sup> consecutive test (excluding inadequate tests) otherwise should be suspended
0	9	S	Maximum 15 months	As per District Settings
0	Q	S	Maximum 15 months	As per District Settings

### 1 = "Inadequate"

New Result Code	Infection Code	Action Code	Repeat Months	
1	9	R	3 months	
1	Q	R	3 months	
1	9	S	Maximum 12 months	As per District Settings
1	Q	S	Maximum 12 months	As per District Settings

**2 = Negative**

Result Code	Infection Code	Action Code	Repeat Months	
2	9	R	12 months	Must not be the 3 <sup>rd</sup> consecutive test (excluding inadequate tests) otherwise should be suspended
2	Q	R	12 months	Must not be the 3 <sup>rd</sup> consecutive test (excluding inadequate tests) otherwise should be suspended
2	9	S	Maximum 15 months	As per District Settings
2	Q	S	Maximum 15 months	As per District Settings

**Result codes 3, 4, 5, 6, 7, 8 & 9**

Result codes 3 to 9 must have an infection code of 9 (HPV positive) or 'Q' (no HPV test undertaken) and will always be suspended from recall. Repeat months will be as the DD screen settings.

Result Codes	Infection Code	Action Code	Repeat Months	
3,4,5,6,7,8,9	9	S	Maximum 12 months	As per District Settings
3,4,5,6,7,8,9	Q	S	Maximum 12 months	As per District Settings

**X = "No Cytology Test Undertaken"**

New Result Code	Infection Code	Action Code	Repeat Months	
X	0	A	36 months if < 50 60 months if >49	As per District Settings
X	0	R	12 or 36 months	
X	0	S	Maximum 15 months	As per District Settings
X	9	S	Maximum 15 months	As per District Settings
X	U	R	3 months	
X	U	S	Maximum 15 months	As per District Settings

The following REJECT messages may be generated if any invalid data items/combinations are entered:

Message	Description
"INFECTION invalid"	Infection must be 9 or Q except if test result is coded X when infection may only be 0 or U.
"INFECTION missing"	Infection code must contain a value if the test result is HPV Primary
"RESULT invalid"	Result code must be 0-9 or X.

"RESULT missing"	Result code must be 0-9 or X.
"ACTION invalid"	Action code must be valid for result code. (A, R or S)
"ACTION missing"	Valid action code must be entered
"COMBINATION invalid"	An invalid combination has been entered such as X0R. Valid combinations are shown in the tables above.
"RPT MTHS invalid for HPV"	An incorrect repeat month's value has been entered for an 'R' coded test. ** Please note that the repeat month's values for 'Suspended' and Negative test results will be set automatically and can't be overridden. **
3rd HPV+ Colp req	If previous 2 NEGATIVE tests (result codes 0 or 2) are coded as 'Repeat Advised' or Early Repeats the new (3 <sup>rd</sup> test) must be coded 'S' to suspend the woman from recall
3rd inad - Colp req	3 <sup>rd</sup> consecutive in adequate result coded 'R'. 3rd test must be coded 'S'. An Inadequate test is deemed to be one with result code 1 or any tests with a infection code of U.

## Sample Screens:

CY]Cytology Test		<b>REJECT</b> Qualifier[977 752 1324 ]	
<b>1. 3rd HPV+ Colp req</b>		page->	
HPV Patient	DoB: 09.06.1962	Age: 50	
Extra Name:	Q Code:QT1	Dr. Vermillion	Code: 000030
10 Any Old Road, EXE	Nat/Local District Code: E10/EX		
EX1 2CC			
Amend/Delete previous tests [Y] Delete ALL Tests [NO ]			
Next Test due [28.12.2013]		PNL Date:	Invited :01.2013
Notif Date [ ]		Recall Type [R] Early Repeat (Normal)	
		Recall Status [-] no Action	
-----			
National Code [1 ]	BISHOP AUCKLAND, CO. DURHAM		Slide No. [13099867]
Test Date [18.1.13 ]	Sender National Code [ ]		
Result Notif [ ]	Source [G]	Sender [ ]	
Result Code [2] Inf [9]	Action Code [R]	Rpt in [12] Months	HPV Primary? [Y]
Correspondence? Y	Age at test date	Input date	Screening HA [TES]
Comment[ ]			]Complete?[ ]
[ ]			]Susp List[Y]
Test 0 of 3	-----T--Flags-----		
Test Date	Result	Infection	Action Code Rpt Mths HPV Primary NB:
28.12.2012	2	9	R 12 Y  FP69: FNR:
14.01.2012	2	Q	R 15 Y  POS/DOUBT :N
12.12.2011	2		A 36 Y  AGE at NTD:

CY]Cytology Test		REJECT Qualifier[977 752 1324 ]	
1. 3rd inad - Colp req		page->	
PATIENT, HPV		DoB: 09.06.1962	Age: 50
Extra Name:	Q Code:QT1	Dr. Vermillion	Code: 000030
10 Any Old Road, EXE		Nat/Local District Code: E10/EX	
EX1 2CC			
Amend/Delete previous tests [Y] Delete ALL Tests [NO ]			
Next Test due [28.04.2013]		PNL Date:	Invited :UNAVAIL
Notif Date [22.01.2013]		Recall Type [I] Early Repeat (Inadequate)	
		Recall Status [1] Patient Informed	
-----			
National Code [1 ]	BISHOP AUCKLAND, CO. DURHAM		Slide No. [13009865]
Test Date [18.1.13 ]	Sender National Code [ ]		
Result Notif [ ]	Source [G]	Sender [ ]	
Result Code [X] Inf [U]	Action Code [R]	Rpt in [ ] Months	HPV Primary? [Y]
Correspondence? Y	Age at test date	Input date	Screening HA [TES]
Comment[			]Complete?[ ]
[			]Susp List[Y]
[			
Test 0 of 3	-----T--Flags-----		
Test Date	Result	Infection	Action Code Rpt Mths HPV Primary NB:
28.12.2012	1	9	R 04 Y  FP69: FNR:
14.01.2012	1	9	R 02 Y  POS/DOUBT :N
12.12.2011	2		A 36 Y  AGE at NTD:

### 8.3 Update

The CY screen update routines have been amended to update the test result details for the new result codes and to set the new recall date according to the rules outlined in 7.1 – validation rules.

The HPV Primary Screening flag will be updated on to the woman's test record as follows:

- Flag set to Y - Sample Method set to Null, HPV Flag remains Y
- Flag set to S - Sample Method set to S, HPV Flag set to Y
- Flag set to N – Sample Method set to Null, HPV Flag set to N

#### 8.3.1 Ceasing 'Due to Age'

A woman whose test result is coded 'X0A' and who passes all other ceasing due to age rules will be ceased automatically if her new recall date is on or after her 65<sup>th</sup> birthday. This applies to the Laboratory Links system and the 'Deducted Transfer' software CINCD. The rules governing ceasing 'due to age' are explained in Section 11 of this document.

## 9 AJ-CD Changes

Minor changes have been made to the CD software to accommodate the new HPV primary screening flag so that the new Result/infection/Action codes can be accommodated. The outgoing electronic transfer file will contain the new flag in order to identify to the receiving NHAIS agency that the test result is a HPV Primary screening result.

The AJ-CD deducted card print has been amended to include the screening flag.

```

(Cervical Cytology Screening Summary Record)

Patients Hpv Mrs.                Deducting HA : TES
NHS No.: WAH 2                  Date of Birth : 23.07.1949
                                Reason for Deduct : MOVEMENT TO NEW HA ( CR )
Asd Exeter Devon                GP Nat Code : 880030
                                Recall Type : Cancelled (C)
                                Recall Status : Cancelled (C Cancelled)
                                Pos/Doubtful : N

                                There is 1 test record to be printed

(Cervical Cytology Screening Test Record)

Patient Hpv Mrs.
NHS No.: WAH 2
Test Date : 17.02.13
Slide No.: 13090986             Screening HA : TES
Result : NEGATIVE (2)           Lab : BISHOP AUCKLAND, CO. DURHAM (60020)
Action Code : A                 Sender : 880030 Source: G
Rpt Months : 60                 GP Nat Code : 880030
HPV Primary : N                 Infection Code :

```

## 10 AJ-CIN Changes (CINCD)

Minor changes have been made to the CINCD software to accommodate the new HPV primary screening flag so that the new Result/infection/Action codes can be accommodated. Redirected test results where the flag is set to "S" or "Y" will be validated according to the Primary screening validation rules. The repeat months will be set as per the HPV primary screening protocols.

The CINCD print reports will display the new result/infection/action code combinations and the HPV Primary Screening flag.

Test results that have been redirected will be highlighted on the AUDIT-Automatic Update to Cytology Details report.

A Non HPV Primary screening redirected test result will display the following message below the Comments line:

\*\*\* This test result from laboratory nnnnnn was redirected via nnnnnnnn HA. A result letter is required \*\*\*\*

An HPV Primary Screening redirected test result will display the following message below the Comments line:

\*\*\* This HPV PRIMARY SCREENING test result from laboratory nnnnnn was redirected via nnnnnnnn HA \*\*\*\*  
 \*\*\* PLEASE NOTE: HPV PRIMARY SCREENING RESULT LETTER is required \*\*\*



## **11 AJ-CP changes**

Minor changes have also been made to the Analysis Job CP to differentiate between HPV Primary screening Districts and Non HPV Primary Screening Districts when selecting the correct result letter for issuing to a woman.

The software will automatically select the correct result letter identifier based on the District, Result code, Infection code and action code.

The HPV Primary Screening letter identifiers are held on a new screen called HP. (See section 6 of the User Guide)

## **12 AJ-RP changes**

Minor changes have also been made to the Analysis Job RP to differentiate between HPV Primary screening Districts and Non HPV Primary Screening Districts when selecting the correct invitation letter or reminder letter identifiers.

The software will automatically select the correct letter identifier based on the District, Result code, Infection code and action code.

The HPV Primary Screening letter identifiers are held on a new screen called HP. (See section 6 of the User Guide)

## Appendix A - Changes to ceasing 'due to age' rules

Amendments will be needed to introduce the new rules governing a woman's automatic ceasing 'due to age'.

### NEW CEASING RULES

As a general rule, any woman whose test is coded 'A' for routine recall can be ceased automatically due to age unless there is an 'abnormal' result in any of her last three tests, including the final one. This is different from the previous rules where the woman had to have had a negative/routine recall test (i.e. one coded 2A or N-0-A).

When assessing if a woman may be ceased 'due to age' or not the following must be taken into account:

- Abnormal test is a test coded 3R, 3S, 4S, 5S, 6S, 7S, 8S, 9R or 9S  
OR  
B9R, B9S, E9S, G9S, M9R, M9S, N9R, N9S or X9S.
- If a woman has an abnormal test result in her history she may only be ceased due to age on the 3<sup>rd</sup> consecutive negative test result following the abnormal result. Private 'H' coded tests (0H, 1H & 2H) and Inadequate (Result code 1R or 1S) tests are discounted when calculating the number of negative test results following the abnormal test result.
- Women who have no abnormal test results

### Ceasing due to age rules are as follows:

If most recent test has an action code of "A" the woman may be ceased as long as:

1. She will be aged 65 or more when her next test is due
2. She has no abnormal tests (result codes 3-9 or HPV positive infection (9) with results coded B, E, G, M, N or X) in her history.
3. She has abnormal test(s) but they were prior to her last 3 normal tests.

Normal tests are:

0A, 0H, 0R, 0S, 09R, 09S, 0QR, 0QS  
1H, 1R, 1S, 19R, 19S, 1QR, 1QS  
2A, 2R, 2S, 29R, 29S, 2QR, 2QS  
B0A, B0R, B0S, BUR, BUS  
E0A, E0R, E0S, EUR, EUS  
G0A, G0R, G0S, GUR, GUS  
M0A, M0R, M0S, MUR, MUS  
N0A, N0R, N0S, NUR, NUS  
X0A, X0R, XUR, X0S, XUS

Abnormal tests are:

3R, 3S, 4S, 5S, 6S, 7S, 8R, 8S, 9R or 9S  
39S, 3QS, 49S, 4QS, 59S, 5QS, 69S, 6QS  
79S, 7QS, 89S, 8QS, 99S or 9QS  
B9R, B9S, E9S, G9S  
M9R, M9S, N9R, N9S or X9S

B9R, M9R & N9R are no longer used but historic tests exist so they need to be taken into account when assessing if a woman may be ceased 'due to age'.

### Abnormal/Normal Results Table

HPV test result ➔  Cytology result ↓	none (HPV triage: no HPV test required)	0 (negative)	9 (positive)	U (no result)	Q (HPV-PS: no HPV test planned)
0	normal	n/a	n/a	n/a	Normal
G	n/a	normal	abnormal	normal	n/a
1	normal	n/a	n/a	n/a	Normal
2	normal	n/a	n/a	n/a	Normal
N	n/a	normal	abnormal	normal	n/a
3	abnormal	n/a	n/a	n/a	Abnormal
M	n/a	normal	abnormal	normal	n/a
4	abnormal	abnormal	abnormal	abnormal	Abnormal
5	abnormal	abnormal	abnormal	abnormal	Abnormal
6	abnormal	abnormal	abnormal	abnormal	Abnormal
7	abnormal	abnormal	abnormal	abnormal	Abnormal
8	abnormal	n/a	n/a	n/a	Abnormal
B	n/a	normal	abnormal	normal	n/a
9	abnormal	n/a	n/a	n/a	Abnormal
E	n/a	normal	abnormal	normal	n/a
X	n/a	normal	Abnormal	normal	n/a